UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

In re CASSAVA SCIENCES, INC. SECURITIES LITIGATION	§	Master File No. 1:21-cv-00751-DAE
	§	CLASS ACTION
This Document Relates To:	§	
ALL ACTIONS	§	

OPPOSED MOTION FOR PARTIAL RELIEF FROM THE PSLRA DISCOVERY STAY

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I. INTRODUCTION

Lead Plaintiff Mohammad Bozorgi and additional plaintiffs Ken Calderone and Manohar Rao (together, "Plaintiffs") respectfully move this Court for an order partially lifting the discovery stay imposed by the Private Securities Litigation Reform Act of 1995 ("PSLRA") for the limited purpose of allowing Plaintiffs to obtain: (i) documents Cassava Sciences, Inc. ("Cassava" or the "Company") produced to the plaintiffs in a related shareholder derivative action recently filed in the Delaware Court of Chancery, *Jeanne M. Calamore, et al. v. Remi Barbier, et al.*, No. 2022-0737-MTZ (Del. Ch. filed Aug. 19, 2022) (the "Derivative Action"), pursuant to an 8 Del. C. §220 books and records demand (the "Demand Documents"); and (ii) documents, interviews, and information Cassava provided to the United States Securities and Exchange Commission ("SEC"), United States Department of Justice ("DOJ"), and the National Institutes of Health ("NIH"), an agency of the United States Department of Health and Human Services (the "Government Productions").

Numerous courts recognize that it is appropriate to lift the PSLRA discovery stay to allow plaintiffs to obtain documents already produced in parallel proceedings. Cassava has previously produced the Demand Documents to the Derivative Action plaintiffs and the Government Productions to the DOJ, SEC, and NIH pursuant to criminal and civil investigations (the "Government Investigations") into the same alleged conduct underlying the allegations in this action. Plaintiffs thus remain the only major party of interest without access to core documents and information exchanged in multiple other proceedings, forcing Plaintiffs to pursue their litigation strategy against a corporation of limited means on behalf of absent putative class members at an informational disadvantage vis-à-vis the parties in related matters.

Under these circumstances, Plaintiffs are unduly prejudiced, and the PSLRA discovery stay should be partially lifted to allow the production of documents that have already been produced in

related litigation to Plaintiffs here. Plaintiffs' requests are particularized, will not burden Defendants,[1] and are consistent with the policies underlying the PSLRA.[2]

II. NATURE AND STAGE OF PROCEEDINGS

Plaintiffs' Claims. Plaintiffs allege that, throughout the Class Period, Defendants engaged in a fraudulent scheme to materially mislead investors regarding the prospects for Cassava's primary product candidate, a purported treatment for Alzheimer's disease, simufilam. ¶80.[3] Unbeknownst to investors, Cassava's pre-clinical and clinical studies justifying the continued commercial development of simufilam contained extensive data manipulation and significant anomalies undermining the validity of the research conducted by Dr. Lindsay Burns, Cassava's Senior Vice President of Neuroscience (who is married Cassava's CEO, Remi Barbier), and Dr. Hoau-Yan Wang, Cassava's longtime scientific collaborator. ¶¶80-104.

Plaintiffs allege that Defendants knew of or recklessly disregarded Cassava's problematic research and clinical trial results, yet failed to disclose these issues in order to qualify for hundreds of millions of dollars' worth of cash bonuses. These bonuses were not tied to meaningful product development milestones; rather the bonuses were tethered to short-term increases in Cassava's stock price under a suspiciously timed executive compensation plan entered into just weeks before the Company released the results of a controversial "reanalysis" of Cassava's Phase 2b clinical trial results, which had previously failed to meet its primary endpoints. ¶¶438-445.

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[1] Collectively, "Defendants" are Cassava, Remi Barbier, Lindsay Burns, Nadav Friedmann, and Eric Schoen.

[2] Pursuant to L.R. CV-7(g), Plaintiffs met and conferred with Defendants on September 7, 2022, but Defendants did not consent to producing the Demand Documents or the Government Productions, as they contend that lifting the stay is improper under these circumstances.

[3] All "¶__" or "¶¶__" are to the Consolidated Complaint for Violation of the Federal Securities Laws ("Complaint"). ECF 68. Additionally, emphasis is added and citations are omitted unless otherwise noted.

Through their materially false and misleading statements, Defendants constructed the façade that Cassava's pre-clinical and clinical trial studies provided "consistent" and favorable results validated by scientific journals. ¶¶252-315. The scheme had its intended effect: during the Class Period, the price of Cassava's common stock skyrocketed, increasing 911% during the first six months of 2021 alone. ¶6. The Company later briefly eclipsed $5 billion in market value, despite not having a single FDA approved drug or any product revenue. *Id*. Due to the spike in Cassava's stock price, Defendants qualified for hundreds of millions of dollars-worth of cash under the new bonus plan. ¶¶465-474.

The truth began to be revealed, however, through a "Citizen Petition" to the United States Food and Drug Administration ("FDA") authored by a pair of doctors-turned-investors who raised "grave concerns" regarding "the quality and integrity of the laboratory-based studies surrounding" simufilam, predicting that Cassava's stock price would fall when those concerns came to light. ¶¶105-130. According to the Citizen Petition, Cassava and Dr. Wang had manipulated and falsified data in a string of academic journals and presentations providing the basis for simufilam's continued commercial development. ¶¶143-251. In response to the Citizen Petition, the Company's share price plummeted $46.98 per share, or 39.9%, between August 25 and 26, 2021, on heavy trading. ¶¶495-498.

Members of the scientific community thereafter reviewed and corroborated the Citizen Petition's concerns regarding the pattern of misconduct in Cassava's research, and numerous papers authored by Drs. Burns and Wang have since been retracted or publicly questioned by scientific journals. ¶¶131-142, 357-359, 408-434. Indeed, nine prominent experts, including a Nobel laureate, went on record with *The New York Times* and other news outlets to state that "they did not trust [Cassava's] methods, results or even the premise underlying [simufilam's] supposed effectiveness." ¶¶40, 122-125, 425-432. And when the respected journal *Science* requested that image analysts

review certain of the Citizen Petition's findings, "[m]any were ***stunned*** by the apparent extreme manipulations in" Cassava-linked cases. ¶¶126-127.

In particular, Dr. Elizabeth Bik, a well-known expert at identifying data manipulation in scientific images, found after investigating the Citizen Petition's claims that "[b]ased on the pattern of irregularities in images in multiple papers," it is "'highly likely that there was some manipulation going on.'" ¶448. And Dr. David Vaux, the Deputy Director of Science Integrity and Ethics at the Australian Walter and Eliza Hall Institute of Medical Research similarly concluded: "It is not conceivable that features in the images (such as apparent duplications) arose due to coincidence (chance) or accident, leaving the only plausible explanation being that the images were ***deliberately*** falsified or fabricated." ¶447.

Yet, rather than investigate the allegations in the Citizen Petition, Cassava's leadership denied the claims out of hand – despite also conceding that their data contained errors – and then attempted to cover up the alleged fraud, first by falsely suggesting in a press release that certain of the misleading Phase 2b results Cassava presented had been generated by the independent lab Quanterix, and second by submitting doctored data to scientific journals questioning the Company's research in order to obtain exculpatory statements from those journals. ¶¶317-362, 386-405, 457-464.

Quanterix, however, issued its own press release days later correcting Cassava's claim. ¶323. Moreover, once the journals made the so-called "original" data supplied by Drs. Burns and Wang publicly available, it became apparent that the images were ***not*** originals and that this new data had itself been manipulated. ¶¶344-354, 389-405. In response, one journal even changed its statement into an "Expression of Concern," indicating that the journal had reason to question the integrity and accuracy of the paper. ¶357.

Today, Barbier continues to spread misinformation regarding the Citizen Petition. During an April 2022 investor conference, Barbier "responded to a question regarding the Citizen's Petition and stated that the FDA denied the petition because they did not find any evidence of fraud." ¶¶411-413. But that is not true. As an analyst that attended the conference pointed out, "[w]hile the FDA did deny the Citizen's Petition, it was ***not*** because the FDA did not find evidence of fraud based on the evidence presented." *Id*. The FDA's response rather explicitly stated that the petition was denied "***solely***" on technical grounds, and that the FDA's response did "not represent a decision by the Agency to take or refrain from taking any action relating to the subject matter of" the petition. *Id*. As discussed below, numerous civil and criminal investigations by regulators and law enforcement have ensued.

The Relevant Investigations. On November 15, 2021, Cassava disclosed that "[c]ertain government agencies have asked us to provide them with corporate information and documents." ¶363. But that was not the whole story. Two days later, on November 17, 2021, *The Wall Street Journal* revealed that "[t]he [SEC] is investigating claims that [Cassava], SAVA . . . manipulated research results of its experimental Alzheimer's drug." ¶367. The investigation followed an August 2021 meeting between the SEC and the authors of the Citizen Petition. *Id*. The article also revealed that the NIH, which provided over $20 million in grants to Cassava, was examining the claims. *Id*.

On July 27, 2022, a *Reuters* article further revealed that the DOJ "opened a criminal investigation into Cassava . . . involving whether the biotech company manipulated research results for its experimental Alzheimer's drug." ¶435. According to the news outlet, the DOJ personnel conducting the investigation "specialize in examining whether companies or individuals have misled or defrauded investors, government agencies or consumers." *Id.*

Then, on August 24, 2022, the parallel Derivative Action plaintiffs filed a Verified Stockholder Derivative Complaint ("Derivative Complaint"), Ex. A.[4] The Derivative Complaint is premised on the Company's aforementioned cash incentive bonus plan and alleges substantially similar facts as alleged here regarding the bonus plan. As in the Complaint (¶¶9-11, 98-104, 465-474), the Derivative Complaint contains allegations: (i) that Cassava executives and directors knew material, nonpublic information concerning the reanalysis of the Company's Phase 2b trial results and then entered into the bonus plan just before publicly announcing the purportedly positive results, ensuring they would benefit (Derivative Complaint, ¶¶2-7, 35, 50-57); (ii) that, under the suspicious bonus plan, the defendants are entitled to excessive compensation, despite the subsequent revelations that simufilam data may have been falsified (*id*., ¶58); and (iii) that the defendants entered into the bonus plan in bad faith and with scienter (*id*., ¶¶80-83). To support these allegations, the Derivative Complaint relied on redacted allegations based on the Demand Documents that Plaintiffs here do not possess. *See generally*, Derivative Complaint.

Procedural Background. Defendants have until October 17, 2022 to file a motion to dismiss the Complaint, which will not be fully briefed until January 16, 2023. ECF 67. Meanwhile, discovery in this litigation has been stayed pursuant to the PSLRA for over 12 months, since August 27, 2021, while the SEC, DOJ, and NIH investigations have continued apace and the Derivative Action plaintiffs have obtained the Demand Documents. Most of the discovery relevant to Plaintiffs' claims likely will be in the control of Cassava, making the Demand Documents and the Government Productions critical to the adjudication of Plaintiffs' fraud claims.

Moreover, Cassava has limited and fast diminishing financial means to resolve these pending litigations and investigations. Currently, Cassava has no marketable products or revenue. ¶82. And

[4] All "Ex._" citations herein are to the Affidavit of Kevin Lavelle in Support of Opposed Motion for Partial Relief from the PSLRA Discovery Stay.

although the Company holds approximately $197 million in cash and equivalents as of June 30, 2022 (August 4, 2022 Form 10-Q, Ex. B at 3, 6), substantially all of these remaining funds are already earmarked and needed for the Company's currently ongoing Phase 3 trials, which, according to the Company, will cost between $200 and $300 million. ¶470-471. Cassava is quickly burning through this remaining cash. The Company spent nearly $37 million in the first six months of 2022 alone (Ex. B, at 3, 6) and expects to spend another $45-$55 million in the second half of 2022. September 13, 2022 Corporate Presentation titled: We focus on Alzheimer's disease, Ex. C at 29.

III. ARGUMENT

The PSLRA imposes a stay of all discovery during the pendency of a motion to dismiss. 15 U.S.C.A. §78u-4(b)(3)(B). However, the stay may be lifted "upon the motion of any party [showing] that particularized discovery is necessary to preserve evidence or to prevent undue prejudice to that party." *Id.* Courts thus have discretion to modify the stay and have routinely done so in cases involving "'concurrent investigations by governmental agencies when doing so would not frustrate Congress' purposes in enacting the PSLRA.'" *Seippel v. Sidley, Austin, Brown & Wood, LLP*, 2005 WL 388561, at *1 (S.D.N.Y. Feb. 17, 2005) (collecting cases).

> In such cases, courts have lifted the stay as to documents which have already been produced to the government, on the ground that the cost of such discovery to defendants is minimal, as the documents have already been compiled for production, while plaintiffs would suffer severe prejudice if discovery in their case is delayed while government investigations and other lawsuits proceed ahead . . . . *Id.*

A. The Discovery Sought Is Particularized and Imposes No Burden

Plaintiffs' requests for the Demand Documents and Government Productions are indisputably particularized. Numerous courts have held that requests limited to productions previously provided to other parties plainly satisfies the particularity requirement. *See, e.g.*, *Waldman v. Wachovia Corp.*, 2009 WL 86763, at *1 (S.D.N.Y. Jan. 12, 2009) ("It is undisputed that the discovery plaintiffs request is sufficiently particularized, as it is limited to a set of documents already provided to state

and federal regulators."); *In re FirstEnergy Corp. Sec. Litig.*, 229 F.R.D. 541, 545 (N.D. Ohio 2004) (request "sufficiently particularized" where "limited to the closed universe of materials . . . already produced" to others).

In addition, because Defendants have already produced the Demand Documents to the Derivative Action plaintiffs and the Government Productions to the DOJ, SEC, and NIH, there is no burden in re-producing the same documents again here. *See In re Enron Corp. Sec., Derivative & "Erisa" Litig.*, 2002 WL 31845114, at *2 (S.D. Tex. Aug. 16, 2002) (no burden where defendant "has already found, reviewed, and organized the documents"); *In re Bank of Am. Corp. Sec., Derivative, & Emp. Ret. Income Sec. Act (ERISA) Litig.*, 2009 WL 4796169, at *3 (S.D.N.Y. Nov. 16, 2009) ("the burden of making another copy for plaintiffs here will be slight").

B. Plaintiffs Are Unduly Prejudiced Without the Requested Documents

"'District Courts have construed undue prejudice to mean improper or unfair treatment amounting to something less than irreparable harm.'" *In re FirstEnergy Corp. Sec. Litig.*, 2021 WL 2414763, at *5 (S.D. Ohio June 14, 2021). "Courts weigh the burden to defendants against the potential prejudice to plaintiffs, focusing on the production costs to defendants and plaintiffs' need for early review of the documents." *Bank of Am.*, 2009 WL 4796169, at *2.

Plaintiffs suffer undue prejudice where, as here, they lack "access to documents produced in . . . other proceedings" and investigations and are therefore "less able to make informed decisions about litigation strategy." *Id.* at *3; *N.Y. State Tchrs.' Ret. Sys. v. Gen. Motors Co.*, 2015 WL 1565462, at *3-*4 (E.D. Mich. Apr. 8, 2015) ("Undue prejudice has been found where the plaintiff lacks access to documents already produced to governmental and other agencies and in other lawsuits."); *Seippel*, 2005 WL 388561, at *1 (same); *FirstEnergy*, 229 F.R.D. at 545 (same); *Singer v. Nicor, Inc.*, 2003 WL 22013905, at *2 (N.D. Ill. Apr. 23, 2003) (same).

The same is true here. Cassava produced documents to the Derivative Action plaintiffs, and in the Government Investigations. Plaintiffs are thus the only major party in any of the several proceedings involving the same core events that have not been provided the sets of documents in question. Absent access to the Demand Documents and Government Productions, Plaintiffs will be forced to pursue this litigation at an unfair informational disadvantage, making the risk of undue prejudice and inconsistent rulings particularly severe. *See Pension Tr. Fund for Operating Eng'rs v. Assisted Living Concepts, Inc.*, 943 F. Supp. 2d 913, 916 (E.D. Wis. 2013) (finding undue prejudice where plaintiff "is fighting this lawsuit in a rapidly shifting landscape, at an informational disadvantage when compared to the many other interested parties").

Modifying the PSLRA discovery stay to allow Plaintiffs to receive copies of the Demand Documents and Government Productions thus "prevents 'undue prejudice' by placing all potential claimants on an equal footing with respect to discovery." *In re Tyco Int'l, Ltd. Multidistrict Litig.*, 2003 WL 23830479, at *4 (D.N.H. Jan. 29, 2003). *See In re Massey Energy Co. Sec. Litig.*, 2011 WL 4528509, at *6 (S.D. W. Va. Sept. 28, 2011) ("It appears that Courts view these circumstances as unfair and allow the lifting of the statutory discovery stay to prevent undue prejudice to the securities litigation plaintiffs . . . .").

Furthermore, resolution of any of the Government Investigations, which have been ongoing since last year, could potentially reduce Cassava's limited (and fast shrinking) resources to settle this action. This too contributes to the prejudice against Plaintiffs. *See Turocy v. El Pollo Loco*, 2017 WL 2495172, at *2 (C.D. Cal. May 10, 2017) (modifying stay where other litigation procedurally ahead of the securities litigation could "potentially diminish El Pollo Loco's resources"); *In re WorldCom, Inc. Sec. Litig.*, 234 F. Supp. 2d 301, 305 (S.D.N.Y. 2002) (undue prejudice found where plaintiffs forced to negotiate for limited funds with less knowledge than other claimants who had access to discovery materials). Plaintiffs thus face the risk that they will be left to pursue their action

against defendants who no longer have as much to offer. *Courter v. CytoDyn, Inc.*, 2022 WL 621535, at *3 (W.D. Wash. Mar. 3, 2022).

C. Plaintiffs' Motion is Consistent with the Intent of the PSLRA

The policies underlying the PSLRA do not support maintaining a stay in cases such as this. "The goal of the PSLRA's discovery stay is to prevent the unnecessary imposition of discovery costs in both money and time on defendants in securities fraud cases." *Singer*, 2003 WL 22013905, at *1. And, as explained above, no such costs would be imposed on Defendants here. Accordingly, maintaining the PSLRA discovery stay here would not protect Defendants from incurring additional discovery costs, but rather would work only to prejudice Plaintiffs by shielding the Demand Documents and Government Productions from Plaintiffs. *See Enron*, 2002 WL 31845114, at *1 ("[T]he PSLRA's discovery stay 'was designed to prevent fishing expeditions in frivolous securities lawsuits' and 'was not designed to keep secret from counsel in securities cases documents that have already become available for review by means other than discovery in the securities case.'"). As such, maintaining the stay as to materials already provided to government entities and other plaintiffs "does not further the policies behind the PSLRA." *FirstEnergy*, 229 F.R.D. at 545; *CytoDyn,* 2022 WL 621535, at *3; *Turocy*, 2017 WL 2495172, at *2.

IV. CONCLUSION

Because "there is no reason to prevent the production of documents that have already been produced or soon will be in another context such as an SEC Investigation or an ERISA action, when the failure to produce will put the securities plaintiff at a strategic disadvantage" (*see In re Royal Dutch/Shell Transp. Sec. Litig.*, 2005 WL 8179784, at *1 (D.N.J. Feb. 15, 2005)), Plaintiffs respectfully request that the Court partially lift the PSLRA discovery stay so that Plaintiffs may obtain the Demand Documents and Government Productions.

DATED: September 30, 2022

Respectfully submitted,

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I hereby certify under penalty of perjury that on September 30, 2022, I authorized the electronic filing of the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the email addresses on the attached Electronic Mail Notice List, and I hereby certify that I caused the mailing of the foregoing via the United States Postal Service to the non-CM/ECF participants indicated on the attached Manual Notice List.

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